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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,736	07/13/2000	David Frederick Horrobin	P65773US0	4938

7590 10/21/2003

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Washington, DC 20004

EXAMINER

PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/21/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/615,736

Applicant(s)

HORROBIN ET AL.

Examiner

Elli Peselev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19, 21-39, 42 and 44-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19, 21-39, 42 and 44-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claims 16-19, 21, 23-34 and 37-39, 42 and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haglund et al for the reasons set forth in the Office Action of May 12, 2003.

Applicant's arguments filed September 11, 2003 have been considered but have not been found persuasive.

Applicant contends that B12 is not an ingredient in the formulations disclosed by Haglund et al.

This argument has been found persuasive with respect to claims 22, 35, 36 and 48. However, note that the formulations of claims 16-19, 21, 23-34, 37-39, 42 and 44-47 are not limited to the presence of vitamin B12 but can contain instead folic acid or vitamin B6. Further, note that Haglund et al disclose the presence of fish oil and Applicant has admitted in his response of April 9, 2003 that "the most obvious source of natural oils containing EFAs is fish oil".

Applicant also contends that Haglund et al discloses administration of 80 mg per day of vitamin B6 and 10 mg per day of folic acid, while the instant claims have been limited to 20 mg per day of vitamin B6 and 5 mg per day of folic acid. This argument has not been found persuasive. Haglund et al teach on page 1361 that the dosage of 80 mg per day of vitamin B6 is a rather high one as it may cause side effects and that dosage of 25 mg per day might be sufficient. Further, note that a person having ordinary skill in the art at the time the instant invention was made would have expected that the lower dosage of vitamins used by applicant might be less effective than the

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dosages shown by Haglund et al. Applicants have not presented any evidence to show that such is not the case.

Claims 16-19, 21-39, 42 and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heijer et al in combination with Horrobin and Huglund et al for the reasons set forth in the Office Action of May 12, 2003.

Applicant has failed to provide any evidence that using lower dosages of vitamins does not result in a formulation which is less effective.

Applicant's arguments filed September 11, 2003 have been considered but have not been found persuasive.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peseliev whose telephone number is 703-308-4616. The examiner can normally be reached on weekdays 8.30 a.m. - 5.00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Elli Peselev

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**ELLI PESELEV
PRIMARY EXAMINER
GROUP 1800**